IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Chatterjee et al.

Serial No.: 08/372,676

Filing Date: 01/07/95

For: Anti-idiotype monoclonal antibody 1A7 and use for the treatment of melanoma and small cell carcinoma

Examiner: J. Reeves

Group Art Unit: 1813

DECLARATION UNDER 37 CFR 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, MALAYA BHATTACHARYA-CHATTERJEE, Ph.D., do hereby declare as follows:

1. Under the name Malaya Chatterjee, I am an inventor for the above-referenced patent application.

2. I am a Member of the Markey Cancer Center in Lexington, and am an Associate Professor in the Department of Internal Medicine, University of Kentucky. My research expertise includes the fields of immunochemistry and molecular oncology. A copy of my *curriculum vitae*, describing my background and qualifications, accompanies this Declaration as *Exhibit A.*

3. In collaboration with the other inventors of the above-referenced patent application, I developed and cloned the 1A7 antibody-producing hybridoma cell line.

4. The cell line was obtained after repeated immunization of BALB/c mice with purified antibody 14G2a. Spleen cells from 4 immunized mice were fused with non-producing mouse myeloma cells and plated in 1200 wells. Supernatants from one of the wells was found to contain antibody reactivity specific for 14G2a but not for isotype or allotype controls. The antibody was also able to inhibit the binding of labeled 14G2a to GD2 expressed on a human cell line. The antibody-producing cells from this well were designated 1A7-1A1. The cells were subsequently cloned by two rounds of limiting dilution. This re-cloned line and the antibody produced thereby are referred to in the above-referenced patent application as 1A7.

5. Progeny of antibody-producing cells from the re-cloned line have been deposited with the ATCC under Accession No. BH-11786. Antibody from the cells has been characterized as described in the above-referenced patent application, and is claimed therein.

6. The 1A7-1A1 cells, the re-cloned 1A7 cell line, the predecessors and progeny thereof, and the antibody produced thereby has been maintained exclusively under the control of myself and the other inventors of the above-referenced application. The cells have been provided outside my laboratory to Dr. Sunil Chatterjee for purposes of ascertaining the sequence of the 1A7 variable region. The transfer was made with the agreement that the cells and the antibody not be redistributed, and that information on the sequence be kept confidential. Purified 1A7 antibody recently entered clinical trials at the University of Kentucky under strict supervision of

Dr. Ken Foon, co-inventor of the patent application. Neither the antibody nor the antibody-producing cells have been available to the public at any time.

7. The DNA and amino acid sequences of the 1A7 variable region genes were determined by Dr. Sunil Chatterjee under my auspices some time after the filing of the above-referenced patent application on January 7, 1995. The 1A7 sequence data have not been disclosed except under terms of confidentiality. The data were included in a recent grant application made to the National Institutes of Health under terms of confidentiality, and it is my understanding that the data will remain confidential until the grant is approved. It is my understanding that a decision on the application has not yet been rendered.

8. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

3/11/96
Date

Malaya Bhattacharya-Chatterjee
Malaya Bhattacharya-Chatterjee, Ph.D.

CURRICULUM VITAE

I. General Information

NAME: Malaya Bhattacharya-Chatterjee, Ph.D.

HOME ADDRESS: 2400 The Woods Lane, Lexington, Kentucky 40502
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SOCIAL SECURITY NO.: 077-46-3416

DATE AND PLACE OF BIRTH: January 16, 1946 - Cooch-Behar, India

PRESENT NATIONALITY: U.S. Citizen

MARITAL STATUS: Married, two children

SPOUSE NAME: Sunil K. Chatterjee, Ph.D.

CHILDREN: Indranil Chatterjee (7/16/77)
Sumana Chatterjee (6/21/80)

II. EDUCATION:

Institution	Degree	Year	Major Field
Presidency College, Calcutta, India	B.S.	1963	Chemistry
University College of Science Calcutta, India	M.S.	1965	Chemistry
University College of Science Calcutta, India	Ph.D.	1969	Biochemistry

III. PROFESSIONAL EXPERIENCE:

Ph.D. Thesis (1966 - April, 1969)

University College of Science, Calcutta, India, Department of Biochemistry: Doctoral studies under the guidance of Prof. S.C. Roy included comparative studies of human normal and malignant cervical epithelial cells with respect to lipid biosynthesis and metabolism.

Postdoctoral studies (1969 - 1971)

Department of Immunology and Immunochemistry, Roswell Park Cancer Institute, Buffalo, New York

Isolation and immunological characterization of urea and alkali-extractable antigens of normal mouse epidermis, methylcholanthrene-induced epidermal hyperplasia, papillomas and squamous cell carcinomas.

Tumor Markers (1972 - 1986)

Roswell Park Cancer Institute, Buffalo, New York

The specific aim involved immunological and immunochemical studies of human tumors and cancer patients with a view towards possible immunodiagnosis and therapy. Major emphasis was placed on ovarian cancer.

Idiotype vaccines against human cancer - (1986 - present).

Roswell Park Cancer Institute, Buffalo, N.Y. and Markey Cancer Center, University of Kentucky:

The specific aim is to evaluate the feasibility of a rational design of idiotype-based anti-tumor therapies. Tumor anti-idiotypic antibodies are developed for clinical trials and at

the same time a better understanding of the underlying principles for their biological effects are sought. Studies also include development of second generation anti-Id vaccines by making anti-Id - Cytokine fusion proteins, anti-Id - Vaccinia Constructs and other DNA vaccines as well as use of different adjuvants and carriers with a view toward improving the immunogenicity of the anti-Id reagents first in suitably developed animal models, then in cancer patients.

IV. ACADEMIC APPOINTMENTS:

Institution	Year	Position held
Roswell Park Memorial Institute, Department of Immunology and Immunochemistry, Buffalo, New York	1969-1971	NIH Postdoctoral Fellow
Roswell Park Cancer Institute, Buffalo, New York, Department of Gynecologic Oncology	1972-1978	Cancer Research Scientist III (Tenured)
Roswell Park Cancer Institute, Buffalo, New York, Department of Gynecologic Oncology	1979-1986	Cancer Research Scientist IV (Tenured)
Department of Clinical Immunology	1987-1991	Cancer Research Scientist IV
Department of Molecular Immunology	1992-1993	Cancer Research Scientist IV
Experimental Pathology Graduate Program, Roswell Park Division, State University of New York at Buffalo	1989-1993	Adjunct Professor
Obstetrics and Gynecology Graduate Program, State University of New York at Buffalo	1989-1993	Adjunct Professor
University of Kentucky, Department of Microbiology and Immunology	1993-1995	Associate Professor
Microbiology and Immunology Graduate Program, University of Kentucky	1993-1995	Member
University of Kentucky, Department of Internal Medicine	1996-present	Associate Professor
Markey Cancer Center, Lexington, KY	1993-present	Member

V. HOSPITAL AND CLINICAL APPOINTMENTS

None

VI. CONSULTING

Consultant for National Institute of Health (NIH).

VII. TEACHING ACTIVITY

Past Teaching Activities at Roswell Park Cancer Institute

I was a faculty member in the Division of Experimental Pathology, Roswell Park Graduate Study Division, State University of New York at Buffalo. This was an adjunct appointment. For the Staff members at Roswell Park, participation in the Graduate Program was voluntary. I participated in lectures, graduate student seminars, intra-departmental graduate divisional meetings and in the development of curriculum. I taught a course PTR535 "Immune Mechanisms and Their Disturbance" which was a required "CORE" course for the Pathophysiology Program. This course was designed for graduate students of Experimental Pathology and was offered twice a year (fall/spring). In this course I taught theoretical bases and practical aspects of immune response, allergies, anaphylaxis, atopy, autoimmunity, immune deficiency and AIDS. I also taught a course on Tumor Immunology (PTR 536) which was offered during the spring semester. I coordinated some of the student seminars and journal club activities.

I advised a large number of students (undergraduate and high school) each year (1982-1992) as part of the Summer Research Program of the Institute. This program attracts outstanding students nationwide and is supported by funds from NSF, NIH and NCI. I have also mentored a number of post-doctoral trainees over the years.

As of February 1st, 1993, I joined the University of Kentucky at Lexington. I became a full member of the Graduate Faculty of the Microbiology Program (1993 - 1995). I participated in the Microbiology seminar course (MI 772) for the graduate students. I have given guest lectures in the BMT Nursing course and Toxicology graduate program.

Current Teaching Responsibilities at University of Kentucky

Course: MI/BIO 611-Biopathology (3 lectures/per semester)

1. Immune Process in Pathological Conditions
2. Arthritis and Glomerulonephritis
3. Cancer Cell Properties as Therapeutic Targets

Course: Methods in Clinical and Basic Research - a team taught course for the Medical Residents of the Hematology Oncology Division, Department of Internal Medicine.

Responsible for teaching basic and clinical aspects of Tumor Immunotherapy.

CourseMI-773 (Preceptor)

To help graduate student for graduate seminar course.

At U.K. a major portion of my teaching efforts have been also related to the mentoring of graduate/undergrad studentes and training M.D./Ph.D. trainees. Hasan Zeytin, M.D. - a graduate student in the Microbiology Program has chosen my laboratory for his Ph.D. Thesis work. I spend a lot of time mentoring his project and helping him as preceptor to prepare for his seminar courses. I have a fellowship grant from the U.S. Department of Army to train post-doctoral fellows in the areas of Breast Cancer Research. We have several funded projects where I have the opportunity to mentor a number of post-graduate trainees.

GRADUATE AND POST-DOCTORAL TRAINEES:

1994 - present	Goutam Sen, Ph.D. (1994) Jadavpur University, Calcutta, India
1993 - present	Amanda Sherrat, Ph.D. (1985) University of Manchester, England; M.D. (1993) University of Kentucky, Lexington, Kentucky
1992 - present	Mala Chakraborty, Ph.D. (1992) Jadavpur University, Calcutta, India
1994 - 1995	Sheila Pervin, Ph.D. (1994) Jadavpur University, Calcutta, India. (She is now a post-doctoral fellow at UCLA, California.)
1991 - 1993	Ewe Mrozek, M.D. (1985) Gdnask University, Poland. (She is now continuing her post-doctoral work at Roswell Park Cancer Institute, Buffalo, New York.)
1989 - 1993	Sonjoy Mukerjee, Ph.D. (1990) from the University of Lucknow, India. (He is now Project Leader, Human Hybridoma Section, NOVOPHARM, San Diego, CA.)

1988 - 1990	Xilin Liu, M.D. (1985) University of Beijing, China. (She is now a Ph.D. student at the University of Quebec, Canada.)
1987 - 1990	Zie Ru Zhang, M.D., University of Beijing, China. (She is now a Clinician, Brooklyn Hospital, New York.)
1984 - 1986	Aniruddha Gangopadhyay, Ph.D. (1984) University of Calcutta, India. (He is now an Asst: Professor at Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts.)
1976 - 1978	Kanakendu Chowdhury, Ph.D. (1974) University of Calcutta, India. (He is at present a Senior Research Fellow in the Dental School of New Jersey Medical College.)

Students

1995 -present	Hasan Zeytin, M.D., Graduate student for Ph.D. Program, Microbiology and Immunology, University of Kentucky
Summer, 1995	Evan Muse, High School Summer Research Student (
May, 1994 - August, 1994	Dianne Lowery Flanagan, Graduate rotation student from Microbiology and Immunology, University of Kentucky
1994 - 1995	Yu Fang, Ph.D. student from the Toxicology Graduate Program, University of Kentucky.
1993 - 1995	Iman Nazhat, B.S. (Biology), University of Kentucky at Lexington. (She is now a Ph.D. student at the University of Colorado at Denver.)
1995 - present	Summer Student Research Program, sponsored by the Markey Cancer Center. This is a 10 week basic and clinical research oriented program for outstanding high school and college students (10 to 12 students). As Co-Director of the Program my responsibility involves selection of the students, orientation lectures, monitoring their progress and supervising the final presentation at the end of their research program.

VIII. ADVISING ACTIVITY

External Doctoral Thesis Advisors

University College of Science, Calcutta, India (1993-)

Jadavpur Unviversity, India (1994-)

IX. ADMINISTRATIVE ACTIVITY AND UNIVERSITY SERVICE

Member, American Cancer Society Institutional Committee (1994 -)
Member, Markey Cancer Center Space Committee (1993 -)
Ad Hoc Member, Markey Cancer Center Recruitment Committee (1993 -)
Member, Faculty Evaluation Committee, Microbiology and Immunology (1993 -1995)
Coordinator, Tumor Immunology Journal Club (1994 -)
Co-Director, Summer Student Research Program sponsored by The Markey Cancer Center (1995 -)
Ad Hoc Member, Medical Student Selection Committee, (Interview Medical Students for Admission) — College of Medicine, University of Kentucky (1995 -)
Coordinator, Radiation Safety and License Committee, Clinical Immunology, RPCI (1987 - 1991)

X. SPECIAL ASSIGNMENTS

Not Applicable

XI. HONORS

Graduated from College with honors in Chemistry and distinction in Physics and Mathematics; Recipient of a Gold Medal for Scholastic Achievements.

Inclusion in Marquis Who's Who in America 1983 - 1985, 1992 - 1996

Inclusion in 17th and 18th Edition of Who's Who of American Women, 1991- 1992.

Inclusion in American Men and Women of Science, 1991-1992.

Inclusion in Who's Who in Science and Engineering, 1996-1997

Member, NIH, Experimental Therapeutics (ET-2) Study Section, 1992-1996

XII. PROFESSIONAL ACTIVITY AND PUBLIC SERVICE

Professional Membership:

1. American Association for Cancer Research	1976 - present
2. The American Association of Immunologists	1981 - present
3. New York Academy of Sciences	1992 - present

NIH Study Section Meetings:

Special Reviewer for Outstanding Investigator Grants (OIG) 1990.

Special Reviewer, Experimental Therapeutics-2 Study Section, February, 1991.

Special Reviewer, Experimental Therapeutics-2, Small Business Grant, AHR B1 Study Section, July, 1991.

Special Reviewer, Experimental Therapeutics-2, Small Research (RO3) Grants, July 29, 1992.

Special Reviewer, Chemistry and Related Sciences Special Emphasis Panel ZRG3 ET-1, April 28, 1995.

Special Reviewer, Experimental Therapeutics-1 Study Section, December 18, 1995.

Member, Experimental Therapeutics-2 Study Section, 1992 - 1996.

NCI Contracts and Conference Grants:

Special Reviewer, NCI Contracts, "Immune-based Therapy in Experimental Animal Models for Human AIDS", June 11-12, 1992.

Special Reviewer, NCI Contracts Source Selection Meeting, October 15, 1992.

Special Reviewer, NCI Conference (R13) Grant, November 4, 1994.

Site Visits:

Program Project Site Visit (Biological Response Modifier Program), November 12-13, 1991.

Program Project on "Antibody Based Therapy for Human Cancer", May 7, 1992.

Program Project Site Visit, "Management of Cancer with Monoclonal Antibodies," May 31 - June 2, 1995.

SPORE Grants:

Reviewer, NCI Special Review Committee for SPORE in Prostate Cancer, July 9-12, 1995.

Ad Hoc Reviewer:

Journal of Immunology
Cancer Research
Cancer Immunology and Immunotherapy
European Journal of Cancer
Journal of the National Cancer Institute
Vaccine Research
Hybridoma

XII. SPEAKING ENGAGEMENTS

Local:

Development of anti-idiotype vaccines against human T cell leukemia/lymphoma. Symposium on "Anti-Idiotype Vaccines", Roswell Park Cancer Institute, September, 1987. (Invited speaker.)

Anti-idiotype approach to cancer therapy. Medical grand rounds, Department of Medicine, Roswell Park Cancer Institute, May, 1989 (Invited).

Anti-idiotype vaccines against human T cell leukemia/lymphoma and GI cancers. Department of Medicine Research Seminar, Roswell Park Cancer Institute, September, 1991 (Invited).

Anti-idiotype approach to therapy of cancer. Department of Medicine Seminar Series, University of Kentucky College of Medicine, September, 1993 (Invited).

Anti-idiotype antibodies as potential therapeutic agents for human cancers. Department of Surgery Research Seminar, University of Kentucky College of Medicine, September 13, 1994 (Invited).

Anti-idiotype antibodies as tumor vaccines. Markey Cancer Center Staff Seminar, April 7, 1995.

Anti-idiotype Antibodies as Vaccines for Human Cancer. Toxicology Graduate Seminar, University of Kentucky, October 23, 1995 (Invited).

State:

Monoclonal antibodies and ovarian cancer antigens. University of Rochester Medical Center, New York, October, 1983. (Invited)

Anti-idiotype (Ab2) vaccine therapy for cutaneous T cell lymphoma (CTCL). Conference on "Specific immunotherapy of cancer with vaccines." The New York Academy of Sciences, Washington, D.C. January 21-22, 1993.

National:

Characterization of human ovarian cystadenocarcinoma-associated antigen. American Association for Cancer Research (AACR) Annual Meeting, San Diego, California, May 1975 (Mini-symposium presentation).

Antigen markers in ovarian cancer. AACR Annual Meeting, mini-symposium presentation, 1980.

Purification of OCAA-1, an ovarian cancer associated antigen from ovarian cystadenocarcinomas. AACR Annual Meeting, mini-symposium presentation, 1981.

Antigenic determinants of human ovarian cystadenocarcinomas defined by monoclonal antibodies. Federation of American Societies for Experimental Biology (FASEB) meeting, mini-symposium, 1982.

Identification of a human cancer-associated glycoprotein, gp-48, defined by monoclonal antibody. AACR Annual Meeting, Mini-symposium, 1982.

Tissue distribution and characterization of a high molecular weight mucin-type glycoprotein reactive with monoclonal antibody 1D3. AACR Annual Meeting, mini-symposium presentation, 1985.

Production and characterization of anti-idiotype antibodies against human T cell acute lymphoplastic leukemia (T-ALL). AAI Annual Meeting, mini-symposisum presentation, 1987.

Idiotype vaccines against human T cell leukemia and lymphoma. IDEC Inc., San Diego, California, December, 1987 (Invited).

Idiotype vaccines against human T cell leukemia and lymphoma. Keystone Symposium, Keystone, Colorado, March, 1988 (Invited).

Monoclonal internal image anti-idiotype for human T cell leukemia antigen. AAI Annual Meeting, Las Vegas, Nevada, April, 1988 (mini-symposium presentation).

Anti-idiotype approach to cancer therapy. University of California at San Diego, Department of Medicine, March, 1989 (Invited).

Syngeneic monoclonal anti-idiotype antibody related to human carcinoembryonic antigen. AAI Annual Meeting, mini-symposium presentation, Washington, D.C., May, 1990.

Anti-idiotype vaccines against human T cell leukemia/lymphoma and GI cancers. San Diego Regional Cancer Center, California, April, 1992 (Invited).

Anti-idiotype antibodies: Novel therapeutic approach to cancer. Seminar organized by Dean's Search Committee, University of Kentucky College of Medicine, October, 1992 (Invited).

Murine anti-idiotype antibody breaks tolerance and induces a specific antibody response to carcinoembryonic antigen in colorectal cancer patients. AAI Annual Meeting, mini-symposium presentation, Anaheim, California, April, 1994.

Anti-idiotype antibodies as potential therapeutic agents for human cancers. Pittsburg Cancer Institute, University of Pittsburgh Medical Center, May 20, 1994 (Invited).

<u>International:</u>

Tumor associated antigens for human cystadenocarcinomas of the ovary. XIth International Cancer Congress, Florence, Italy, October, 1974 (Recipient of UICC Travel Grant).

Ovarian tumor antigen. Invited symposium speaker at the Second International Congress on Carcinoembryonic Antigen, Organized by Ephraim McDowell Cancer Foundation, Lexington, Kentucky, June 2-5, 1977.

Use of ovarian tumor-associated antigens for the detection and management of ovarian carcinoma. XIIth International Cancer Congress, Buenos Aires, Argentina, October 5-11, 1978. (Recipient of UICC Travel Grant).

Ovarian cancer antigens, International Workshop, one of the organizers and invited participant, London, England, September 1-5, 1979.

Study of monoclonal hybridoma antibodies against human ovarian cystadenocarcinomas. XIIIth International Cancer Congress, Seattle, Washington, September 8-15, 1982. (Recipient of UICC Travel Grant).

Monoclonal antibodies and ovarian cancer antigens. Invited keynote speaker, International Conference on Cancer Research, organized by C. R. National Cancer Institute, Calcutta, India, February 28 - March 1, 1984.

Mucinous ovarian and colon carcinoma antigens defined by monoclonal antibody 1D3, XIVth International Cancer Congress, Budapest, Hungary, August, 1986. (Recipient of UICC Travel Grant.)

Idiotype vaccines against human gastrointestinal (GI) carcinoma, XVth International Cancer Congress, Hamburg, West Germany, August 16-22, 1990. (Recipient of NCI Travel Grant.)

Anti-idiotype antibodies: Novel therapeutic approaches to breast cancer. Plenary lecture. 5th International Workshop on Breast Cancer Therapy and Immunology, San Francisco, California, November 16-17, 1992 (Invited).

Active immunotherapy of colorectal cancer patients with monoclonal anti-idiotype antibody. Invited symposium speaker, XVIth International Cancer Congress, New Delhi, India, October 30 - November 5, 1994. (Recipient of NCI Travel Grant.)

Immunotherapy of Cancer with anti-idiotype antibodies. Indian Institute of Chemical Biology, Calcutta, November 23, 1994 (Invited).

XIV. RESEARCH AND/OR CREATIVE PRODUCTIVITY

PUBLICATIONS (A Total of 63 Full Length Manuscripts and 52 Abstracts)

1. **Bhattacharya, M.**: Studies in Human Malignant Tissues (Ph.D. Thesis, done under the direction of Prof. S.C. Roy, Head of the Department of Biochemistry, Calcutta, India, 1969).

1a. Peer-reviewed original research

1. **Bhattacharya, M**. and Carruthers, C.: Problems Involved in the Isolation of Subcellular Fractions from Human Epidermis. J. Soc. Cosmet .Chem. 22:95-107, 1971.

2. **Bhattacharya, M**. and Carruthers, C.: Antigenic Differences Between normal Mouse Epidermis and Methylcholanthrene-Induced Squamous Cell Carcinoma. Oncology 26:1-15, 1972.

3. Carruthers, C. and **Bhattacharya, M.**: Correlation Between Various Proteins of Bovine Snout Epidermis. Br. J. Derm. 86:494-505, 1972.

4. Carruthers, C. and **Bhattacharya, M.**: Antigenic Changes in Mouse Epidermis at Various Stages of Neoplastic Transformation. GANN 63:299-305, 1972.

5. **Bhattacharya, M**. and Barlow, J.J.: Immunologic Studies of Human Serous Cystadenocarcinoma of the Ovary. Demonstration of Tumor-Associated Antigens. Cancer 31:588-595, 1973.

6. **Bhattacharya, M**. and Barlow, J.J.: An Immunologic Comparison Between Serous Cystadenocarcinoma of the Ovary and other Human Gynecological Tumors. Am. J. Obstet. and Gynecol. 117:849-953, 1973.

7. **Bhattacharya, M.**, Barlow, J.J., Chu, T.M. and Piver, M.S.: Tumor-Associated Antigen(s) from Granulosa Cell Carcinomas of the Ovary. Cancer Res. 34:818-822, 1974.

8. Barlow, J.J. and **Bhattacharya, M.**: Tumor-Markers in Ovarian Cancer: Tumor-Associated Antigens. Semin. Oncol. Vol. II, No. 3:203-209, 1975.

9. **Bhattacharya, M.**, Barlow, J.J., Allen, H.J., Chung, W.S. and Piver, M.S.: Lymphocyte Response to Autologous Tumor Antigen(s) and Phytohemagglutinin in Ovarian Cancer Patients. Cancer 36:956-962, 1975.

10. **Bhattacharya, M.**, Chatterjee, S.K. and Barlow, J.J.: UDP-Galactose: Glycoprotein Galactosyltransferase Activity in the Ovarian Cancer Patients. Cancer Res. 31:2096-2101, 1976.

11. Barlow, J.J. and **Bhattacharya, M.**: Tumor Marker in Ovarian Cancer. Tumor-Associated Antigen. N.Y. State J. Med. 77: 342-343, 1977.

12. Chatterjee, S.K., **Bhattacharya, M.** and Barlow, J.J.: Elevated Activity of Cytidine 5'-Monophospho-N-Acetylneuraminic Acid Hydrolase in Serum of Ovarian Cancer Patients as a Possible Indicator of Malignancy. Biochem. Biophys. Res. Commun. 80:826-832, 1978.

13. **Bhattacharya, M.** and Barlow, J.J.: Ovarian Tumor Antigens. Cancer 42:220-224, 1978.

14. Chatterjee, S.K., **Bhattacharya, M.** and Barlow, J.J.: Correlation of UDP-Galactose Glycoprotein: Galactosyltransferase Levels in the Sera With the Clinical Status of Ovarian Cancer Patients. Cancer Letters 5:239-2444, 1978.

15. Piver, M.S., Barlow, J.J. and **Bhattacharya, M.**: Treatment and Immunodiagnosis of Advanced Ovarian Adenocarcinoma. Cancer Treat. Rep. 63:265-268, 1979.

16. Piver, M.S., Barlow, J.J. and **Bhattacharya, M.**: Diagnosing, Staging and Treating Early Ovarian Carcinoma. Contemp. Ob/Gyn. 14:33-38, 1979.

17. Chatterjee, S.K., **Bhattacharya, M.** and Barlow, J.J.: Glycosyltransferase and Glycosidase Activities in Ovarian Cancer Patients. Cancer Res. 39:1943-1951, 1979.

18. Chatterjee, S.K., **Bhattacharya, M.** and Barlow, J.J.: A Simple, Specific Radiometric Assay for 5'-Nucleotidase. Anal. Biochem. 95:497-507, 1979.

19. Chatterjee, S.K., **Bhattacharya, M.** and Barlow, J.J.: Determination of Serum Galactosyltransferase Levels in Ovarian Cancer Patients for the Evaluation of the Effectiveness of Therapeutic Programs. Cancer Letters 8:247-253, 1980.

20. Chatterjee, S.K., **Bhattacharya, M.** and Barlow, J.J.: Evaluation of 5'-Nucleotidase as an Enzyme Marker in Ovarian Carcinoma. Cancer 47:2648-2653, 1981.

21. Cantarow, W.B., Stolbach, L.L., **Bhattacharya, M.**, Chatterjee, S.K. and Barlow, J.J.: The Value of Tumor Markers in Cancer of the Ovary. Int. J. Radiat. Oncol. Biol. Phys. 7:1095-1098, 1981.

22. Chatterjee, S.K., Chowdhury, K., **Bhattacharya, M.** and Barlow, J.J.: β-Hexosaminidase Activities and Its Isoenzymes in Normal Human Ovary and Ovarian Adenocarcinoma. Cancer 49:128-135, 1982.

23. Choudhury, K., Chatterjee, S.K., **Bhattacharya, M.** and Barlow, J.J.: Inhibition of Galactosyltransferase by 5-Fluorouracil. Biochem. Pharm. 31:459-460, 1982.

24. **Bhattacharya, M.**, Chatterjee, S.K., Barlow, J.J. and Fuji, H.: Monoclonal Antibodies Recognizing Tumor-Associated Antigen of Human Ovarian Mucinous Cystadenocarcinomas. Cancer Res. 42:1650-1654, 1982.

25. Barlow, J.J. and **Bhattacharya, M.**: Tumor-Associated Antigens for Cystadenocarcinoma of the Ovary. Clin. Obstet. Gynecol. 10:187-196, 1983.

26. **Bhattacharya, M.**, Chatterjee, S.K., and Barlow, J.J.: Identification of a Human Cancer-Associated Antigen Defined with Monoclonal Antibody. Cancer Res. 44:4528-4534, 1984.

27. Chatterjee, S.K., **Bhattacharya, M.**, and Barlow, J.J.: Murine Monoclonal Antibodies Against Galactosyltransferase from the Ascites of Ovarian Cancer Patients. Cancer Res. 44:5723-5732, 1984.

28. **Bhattacharya, M.**, Chatterjee, S.K., Gangopadhyay, A. and Barlow, J.J.: Production and Characterization of Monoclonal Antibody to a 60 Kd Glycoprotein in Ovarian Carcinoma. Hybridoma 4:153-162, 1985.

29. Gangopadhyay, A., **Bhattacharya, M.**, Chatterjee, S.K., Barlow, J.J. and Tsukada, Y.: Immunoperoxidase Localization of a High Molecular Weight Mucin Recognized by Monoclonal Antibody 1D3. Cancer Res. 45:1744-1752, 1985.

30. Chatterjee, S.K., **Bhattacharya, M.**, and Barlow, J.J.: Biochemical and Immunologic Characterization of Glactosyltransferase Purified from the Ascites of Ovarian Cancer Patients. J. Natl. Cancer Inst. 75:237-248, 1985.

31. **Bhattacharya, M.**, Chatterjee, S.K., Gangopadhyay, A., and Barlow, J.J.: Production of Murine Monoclonal Antibodies Against Cell Surface Antigens of Human Ovarian Carcinoma. J. Surg. Oncol. 30:209-214, 1985.

32. Chatterjee, S.K., **Bhattacharya, M.**, and Barlow, J.J.: Characterization of Products Synthesized by Galactosyltransferase Purified from the Ascites of Ovarian Cancer Patients. J. Natl. Cancer Inst. 77:855-862, 1986.

33. **Bhattacharya-Chatterjee, M.**, Pride, M.W., Seon, B.K. and Kohler, H.: Idiotype Vaccines Against Human T-Cell Acute Lymphoblastic Leukemia (T-ALL). I. Generation and Characterization of Biologically Active Monoclonal Anti-Idiotypes. J. Immunol. 139:1354-1360, 1987.

34. Gangopadhyay, A., Barlow, J.J., Petrelli, N.J., Tsukada, Y. and **Bhattacharya-Chatterjee, M.**: Expression of a High Molecular Weight Mucin-Type Glycoprotein in Human Colon Cancer as Defined by Monoclonal Antibody 1D3. Hybridoma 7:141-154, 1988.

35. **Bhattacharya-Chatterjee, M.**, Chatterjee, S.K., Vasile, S., Seon, B.K. and Kohler, H.: Idiotype Vaccines Against Human T Cell Leukemia. II. Generation and Characterization of a Monoclonal Idiotype Cascade (Ab1, Ab2 and Ab3). J. Immunol. 141:1398-1403, 1988.

36. Gangopadhyay, A., Chatterjee, S.K., **Bhattacharya, M**. and Barlow, J.J.: Characterization of the antigen recognized by monoclonal antibody 1D3. Cancer Biochem. Biophys. 10:107-115, 1988.

37. **Bhattacharya-Chatterjee, M.**, and Kohler, H.: Anti-idiotype Tumor Vaccines. Adv. Exp. Med. Biol. 251:113-128. 1990.

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1b. Non-peer reviewed work (invited articles, reviews, symposium proceedings)

(i) **Bhattacharya-Chatterjee, M.** and Kohler, H.: Anti-Idiotype Tumor Vaccines. In: Immunobiology of Proteins and Peptides. V. M. Z. Atassi (ed), Plenum Publishing Corp. p 113-127, 1989.

(ii) Kohler, H., Muller, S., **Chatterjee, M.**, and Foon, K.A. Therapeutic anti-clonotypic Antibodies. Proceed. 8th International Congress Immunol., Springer Verlag, 619-626, 1992.

(iii) **Bhattacharya-Chatterjee, M.**, Chakraborty, M., Kohler, H., Sherratt, A.J., and Foon, K.A. Active Immunotherapy of Colorectal Cancer Patients with Murine Monoclonal Anti-Idiotype Antibody. Proceed. XVIth Internat. Cancer Congress, Monduzzi, M., Editor, 2:495-499, 1994.

2. Books and Book Chapters:

I. **Bhattacharya, M**. and Barlow, J.J.: Tumor-Specific Antigens Associated With Human Ovarian Cystadenocarcinoma. In: The Handbook of Cancer and Immunology. H. Waters, Ed., New York, Garland Publishing Inc., Vol. 4, Chapter 10, 1979.

II. **Bhattacharya, M**. and Barlow, J.J.: Ovarian Cancer. In: Immunodiagnosis of Cancer, R.B. Herberman and K.R. McIntire (Eds.), New York, Marcel Dekker, Inc., P.632-643, 1979.

III. **Bhattacharya, M.** and Barlow, J.J.: Assay Summary for Ovarian Cystadenocarcinoma-Associated Antigen (OCAA). In: Compendium of Assays for Immunodiagnosis of Human Cancer. R.B. Herberman, (Ed.), Elsevier Publishing, Inc., New York, P.527-531, 1979.

IV. **Bhattacharya, M**. and Barlow, J.J.: Tumor Markers for Ovarian Cancer. In: Int. Adv. in Surg. Oncol., G.P. Murphy (Ed.), Alan R. Liss, Inc., New York, Vol. 2, p.155-176, 1979.

V. **Bhattacharya, M**., Chatterjee, S.K., and Barlow, J.J.: Ovarian Tumor Antigens and Other Tumor Markers. In: Textbook on Ovarian Cancer. C.N. Hudson (Ed.), Oxford Press, London, U.K., p. 169-189, 1985.

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VII. **Bhattacharya-Chatterjee, M.,** Mrozek, E., Mukerjee, S., Ceriani, R.L., Kohler, H., and Foon, K.A.: Anti-Idiotype Antibodies as Potential Therapeutic Agents for Human Breast Cancer In: Antigen and Antibody Molecular Engineering in Breast Cancer Diagnosis and Treatment, R.L. Ceriani (Ed.), Plenum Press, N.Y., pp. 139-148, 1994.

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Antibodies", Rosenberg, M. and Moore, G. (Eds.) Springer-Verlag, Heidelberg, Germany, Chapter 16, pp. 387-401, 1994.

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X. **Bhattacharya-Chatterjee, M**. and Foon, K.A. Tumor Markers and Immunotherapy of Cancer. In: Clinical Immunology, (a multi-authored textbook), P.C. SenGupta (Ed.) Oxford University Press (Manuscript submitted).

XI. **Bhattacharya-Chatterjee, M.**, Kohler, H., and Foon, K.A. Idiotypes in Cancer. In: Idiotypes in Medicine - Infections, Autoimmunity and Cancer, Ferrone/Kennedy (Eds), Elsevier Science, Amsterdam, The Netherlands (communicated).

3. Monograph:

Bhattacharya, M. and Barlow, J.J.: A Tumor-Associated Antigen from Cystadenocarcinomas of the Ovary. Natl. Cancer Inst. Monog. 42:25-32, 1975.

7. Abstracts:

1. **Bhattacharya, M**. and Barlow, J.J.: Tumor-Associated Antigen(s) from Human Cystadenocarcinoma of the Ovary. XIth International Cancer Congr., Florence, Italy 2:105, 1974.

2. Barlow, J.J., **Bhattacharya, M**. and Piver, M.S.: Ovarian Cystadenocarcinoma Antigen. Annual Meeting of the Society of Gynecologic Oncologists, Key Biscayne, Florida, 1974.

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33. **Bhattacharya-Chatterjee, M.**, W. Biddle, K.A. Foon, and H. Kohler. Idiotype vaccines against human gastrointestinal (GI) carcinoma. 15th International Cancer Congress, Hamburg, West Germany, August 16-22 1990.

34. **Bhattacharya-Chatterjee, M.**, K.A. Foon, J. Zhang, N. Petrelli and H. Kohler. Idiotype matching: Level of expression of a network antigen idiotype in colon cancer patients' sera. FASEB J. 5:A1356, 1991.

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39. **Chatterjee, M.**: Anti-idiotype antibodies: Novel therapeutic approaches to breast cancer. **Plenary Lecture. 5th Internatl. Workshop on Breast Cancer Therapy and Immunology, San Francisco, CA, Nov. 16-17, 1992**.

40. **Chatterjee, M**., Mrozek, E., Vaickus, L., Oseroff, A., Stoll, H., Russel, D., Kohler, H. and Foon, K.A.: Anti-idiotype (Ab2) vaccine therapy for cutaneous T cell lymphoma (CTCL). Conference on "Specific Immunotherapy of Cancer with Vaccines". The New York Academy of Sciences, Washington, D.C., January 21-24, 1993.

41. **Bhattacharya-Chatterjee, M.**, Mrozek, E., Chakraborty, M., Reisfeld, R.A., Kohler, H., and Foon, K.A.: Syngeneic monoclonal anti-idiotype antibodies against a monoclonal antibody to human melanoma associated antigen. J. Immunol. 150:142A, 1993.

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43. Chakraborty, M., Foon, K.A., Köhler, H. and **Bhattacharya-Chatterjee, M**. Murine Monoclonal Anti-Idiotype Antibody Induces a Specific Antibody Response to Human Carcinoembryonic Antigen (CEA) in Cynomolgus Monkeys. FASEB J. A504, 1994.

44. **Bhattacharya-Chatterjee, M.**, Chakraborty, M., Köhler, H., Sherratt, A.J., and Foon, K.A. Murine Anti-idiotype (Id) Monoclonal Antibody (mAb) Breaks Tolerance and Induces a Specific Antibody Response to Carcinoembryonic Antiben (CEA) in Colorectal (CRC) Cancer Patients. FASEB J. A200, 1994. (Presented at a mini-symposium of the Annual AAI Meeting, Anaheim, CA, April, 1994.)

45. **Bhattacharya-Chatterjee, M.**, Chakraborty, M., Köhler, H., Sherratt, A.J., and Foon, K.A. Active Immunotherapy of Colorectal Cancer Patients with Murine Monoclonal Anti-Idiotype Antibody. Symposium Presentation at the XVI International Cancer Congress, New Delhi, India, October 30 - November 5, 1994.

46. Foon, K.A., Chakraborty, M., **Bhattacharya-Chatterjee, M.** Murine Anti-Idiotype (Id) Monoclonal Antibody (mAb) Induces Specific Humoral Responses to Carcino-embryonic Antigen (CEA) in Colorectal Cancer (CRC) Patients. Abstract presented at the American Association Clinical Oncology (ASCO), Dallas, TX, May, 1994. (Mini-symposium)

47. Sen, G., Chakraborty, M., Foon, K.A., Reisfeld, R.A., and **Bhattacharya-Chatterjee, M.** Murine Monoclonal Anti-Idiotype Antibody Breaks Tolerance and Induces Specific Antibody Response to Human Disialoganglioside GD2 in Cynomolgus Monkeys. Abstract presented at the 9th International Congress of Immunology, San Francisco, California, July 23-29, A5250, p. 885, 1995.

48. Pervin, S., Sherratt, A., Wang, H-T., Blalock, E.J., **Bhattacharya-Chatterjee, M.,** Köhler, H., Foon, K.A., and Chatterjee, S.K. Proliferation of T-cells from colon cancer patients by peptides based on the structure of an anti-idiotype antibody mimicking CEA. Abstract submitted for presentation at the American Association for Cancer Research Annual Meeting, Washington, DC, April 20-24, 1996.

49. Foon, K.A., Chatterjee, S., Chakraborty, M., John, W.J., Sherratt, A., and **Bhattacharya-Chatterjee, M.** Anti-Idiotype Antibody Vaccine (3H1) that Mimics the Carcinoembryonic Antigen (CEA) as Adjuvant Treatment. Abstract submitted for presentation at the American Society for Clinical Oncologists Annual Meeting, Philadelphia, PA, May 18-21, 1996.

50. Sen, G., Chakraborty, M., Foon, K.A., Reisfeld, R.A., and **Bhattacharya-Chatterjee, M.** An alternative Strategy for Inducing Predominately IgG Antibodies and T cell Responses Against Disialoganglioside GD2 Using An Anti-Idiotype Antibody. Abstract submitted for presentation at the ASBMB/ASIP/AAI Joint Meeting, New Orleans, LA, June 2-6, 1996.

51. Chakraborty, M., Foon, K.A., and **Bhattacharya-Chatterjee, M.** Serological Response Patterns of Colorectal Cancer (CRC) Patients Immunized with an Anti Idiotype Antibody. Abstract submitted for presentation at the ASBMB/ASIP/AAI Joint Meeting, New Orleans, LA, June 2-6, 1996.

52. Chatterjee, S.K., Tripathi, P.K., Qin, H-X., Xu, C., Foon, K.A., and **Bhattacharya-Chatterjee, M.** Construction of Vectors for Expression of Functional Anti-

Idiotype Antibody Fragments. Abstract submitted for presentation at the ASBMB/ASIP/AAI Joint Meeting, New Orleans, LA, June 2-6, 1996.

MANUSCRIPTS UNDER PREPARATION

1. Sen, G., Chakraborty, M., Foon, K.A., Reisfeld, R.A., and **Bhattacharya-Chatterjee, M.**: An Alternative Strategy forr Inducing Predominately IgG Antibodies and T cell Responses Against Dialoganglioside GD2 using an Anti-Idiotype Antibody. J. Immunol. (Ready for communication).

2. Sen, G., Chakraborty, M., Foon, K.A., Reisfeld, R.A., and **Bhattacharya-Chatterjee, M.**: Pre-Clinical Studies of an Anti-Idiotype Antibody 1A7 mimicking GD2 in cynomolgus Monkeys (for Cancer Research).

3. Foon, K.A., Sherratt, A.J., Chakraborty, M., John, W., and **Bhattacharya-Chatterjee, M.**: Anti-Idiotype Immunization Induces Active Immunity to Carcinoembryonic Antigen in Colon Cancer Patients Simultaneously Treated with 5FU/Levamisole. A Study of Four Cases (for Clinical Cancer Research -- Advances in Brief).

4. Chakraborty, M., Sherratt, A.J., Foon, K.A., John, W., Sen, G., and **Bhattacharya-Chatterjee, M.**: Active Specific Immunotherapy for GI Cancer: Phase I Trial of Twenty-five Patients with Anti-idiotype Antibody 3H1 That Mimics Carcinoembryonic Antigen (for J. Clin. Oncology).

5. Pervin, S., Sherratt, A.J., **Bhattacharya-Chatterjee, M.**, Blalock, E., Kohler, H., Foon, K.A., and Chatterjee, S.K.: Study of T Cell Peptides Derived from Sequences of Anti-Id 3H1 which Mimicks Carcinoembryonic Antigen (for Immunology or J. Immunology).

6. Pervin, S., Chakraborty, M., Zeytin, H. **Bhattacharya-Chatterjee, M.**, Foon, K.A., and Chatterjee, S.K.: Vaccination with a murine monoclonal anti-idiotype that mimics human carcinoembryonic antigen protects C57BL/6 mice against CEA-transfected tumor cell challenge (For Cancer Immunology Immunotherapy).

GRANT ACTIVITY

EXISTING GRANTS

I. **Source and Identifying Number:** USAMRDC, AIBS # 184; **Title:** Development of Anti-Idiotype Monoclonal Antibodies for the Treatment of Breast Cancer; **Your Role on Project:** Principal Investigator; **% Effort:** 5; **Dates and Cost of Entire Project:** 7/1/94-6/30/97, $129,771; **Specific Aims of Project:** This is a fellowship grant which involves mentoring the M.D. Ph.D. fellow for the development of anti-idiotype antibodies for breast cancer treatment.

II. **Source and Identifying No.:** NCI Program Grant U01-CA 65748-01; **Title:** New Approaches to Breast Cancer Therapy; **Your Role on Project:** Program Leader of Research Project I; **% Effort:** 20; **Dates and Costs of Entire Project:** 1/1/95 - 12/31/98, $879,410; **Specific Aims of Project:** Contains two projects, (1) Clinical Trial of Breast Cancer Patients with Anti-Idiotype Antibodies and (2) Development of Second Generation Anti-Idiotype Antibodies (Ab2-Cytokine Fusion Proteins).

III. **Source and Identifying No.:** NIH R01 CA-60000-01 Grant; **Title:** Anti-Idiotype Vaccine for Breast Cancer; **Your Role on Project:** Co-Principal Investigator; **% Effort:** 30; **Dates and Costs of Entire Project:** 12/1/94 - 11/30/97, $711,335; **Specific Aims of Project:** Phase Ib Clinical Trial of Breast Cancer Patients with Monoclonal Anti-Idiotype Antibody.

IV. **Source and Identifying Number:** Ephraim McDowell Foundation; **Title:** $CD44_V$, a Target for Vaccine Therapy; **Your Role on Project:** Principal Investigator; **% Effort:** 5; **Dates and Cost of Entire Project:** 1/1/94-6/30/96, $10,000; **Specific Aims of Project:** Generation of Anti-Idiotype Antibodies Against $CD44_V$ for Immunotherapy in Rat Carcinoma Model.

GRANT SUPPORT (During Last 4 Years)

I. **Source and Identifying Number:** NIH RO1 CA47860; **Title:** Idiotype Approach to Therapy of Human T Cell Leukemia; **Your Role on Project:** Principal Investigator; **% Effort:** 50; **Dates and Cost of Entire Project:** 5/1/89-4/30/93; $314,106; **Specific Aims of Project:** Immunotherapy of human T cell leukemia/lymphoma with anti-idiotype antibody.

II. **Source and Identifying No.:** NIH 1P01 CA 57165 (Program Project); **Title:** Monoclonal Antibody Therapy of GI Cancers; **Your Role on Project:** Principal Investigator for Project I; **% Effort:** 20; **Dates and Costs of Entire Project:** 9/30/91 - 8/31/95, $322,438 (for Project I); **Specific Aims of Project:** Focuses on the applications of monoclonal anti-idiotype antibodies for the therapy of gastrointestinal tumors.

III. **Source and Identifying Number:** NIH 1RO1 CA56701; **Title:** Structure-Function of Tumor-Anti-Idiotypic Antibodies; **Your Role on Project:** Principal Investigator for the Consortium; **% Effort:** 10; **Dates and Cost of Entire Project:** 9/30/91 - 8/31/95, $160,902, total direct costs for Consortium; **Specific Aims of Project:** Generation of tumor anti-idiotypic antibodies and determine structure-function relationship among Ab1-Ab2-Ab3.

IV. **Source and Identifying No.:** The Share Foundation; **Title:** Anti-Idiotype Vaccine for Melanoma; **Your Role on Project:** Co-Principal Investigator; **% Effort:** 10; **Dates and Costs of Entire Project:** 1/1/94 - 4/30/95, $75,000; **Specific Aims of Project:** To develop anti-idiotype antibodies for immunotherapy of melanoma.

V. **Source and Identifying Number:** The Council for Tobacco Research (CTR); **Title:** Anti-Idiotype Vaccine for Small Cell Lung Carcinoma; **Your Role on Project:** Co-Principal Investigator; **% Effort:** 10; **Dates and Cost of Entire Project:** 7/1/94-6/30/95, $79,900; **Specific Aims of Project:** Phase I Clinical Trial of Small Cell Lung Carcinoma Patients with Anti-Idiotype Antibody.

VI. **Source and Identifying Number:** NCI Travel Grant; **Cost:** $3,000; **Specific Aims:** Invited Symposium Speaker in the 16th International Cancer Congress in New Delhi, India, on October 30 -November 5, 1994.

GRANTS (Pending)

I. **Source:** NIH R01 Grant; **Title:** Ganglioside GD2 as a Target for Immunotherapy in Melanoma; **Your Role on Project:** Principal Investigator; **% Effort:** 25; **Dates and Costs of Entire Project:** 7/01/96 - 6/30/2001, $ 1,035,000 total direct cost; **Specific Aims of Project:** Immunotherapy of human melanoma with anti-idiotype antibody and DNA-based vaccines.

II. **Source:** NIH.R01 Grant, **Title**: Immunotherapy of Cancer with Anti-Id Based DNA Vaccines; **Your Role on Project:** Co-Principal Investigator; **% Effort:** 20; **Dates and Costs of Entire Project:** 12/01/96 - 11/30/00, $ 1,029,885 total direct cost; **Specific Aims of Project:** To develop novel therapueutic vaccines for cancer patients using internal image anti-idiotype antibodies (anti-Id), designated 3H1

which mimics carcinoembryonic antigen (CEA) and can be used as a surrogate antigen for CEA.

III. **Source:** NIH U01 Program Grant; **Title:** New Therapuetic Approaches to Colon Cancer; **Your Role on Project:** Principal Investigator of Project; **% Effort:** 20; **Dates and Costs of Entire Project:** 09/01/96 - 08/31/99, $ 1,254,608 total direct cost; **Specific Aims of Project:** To develop new immunotherapy for patients with colon carcinoma using the internal image antigen based DNA vaccines.

IV. **Source:** NIH R03 Grant; **Title:** Comparison of Alum and QS-21based Anti-Id Vaccine; **Your Role on Project:** Co-Principal Investigator; **% Effort:** 5; **Dates and Costs of Entire Project:** 12/1/96 - 11/30/98; $ 100,000 total direct cost; **Specific Aims of Project:** Compare immune rresponses in patients induced by Alum precipitated versus QS-21 mixed vaccine.

V. **Source:** American Cancer Society; **Title:** DNA Vaccines Based on an Anti-Idiotype Antibody Mimicking CEA; **Your Role on Project:** Co-Investigator; **% Effort:** 10; **Dates and Costs of Entire Project:** 7/1/96 - 6/30/99, $352,000; **Specific Aims of Project:** To develop and characterize DNA vaccines in animal models.

PREVIOUS GRANT SUPPORT

American Cancer Society. "Idiotype Vaccines Against Human T Cell Leukemia and Lymphoma"; 7/1/89-6/30/91; $160,000; M. Chatterjee, Ph.D., Principal Investigator.

IDEC, Inc., Mountainview, CA. "Expression of Shared Anti-Idiotypes in Human B-Cell Leukemia and Lymphoma". 1989 - 1992; $15,000 per year; M. Chatterjee, Ph.D., Co-PI.

Buffalo Foundation Grant, 857-0484A, "Feasibility Study of Anti-Idiotype Vaccine for Cutaneous T Cell Lymphoma". M. Chatterjee, Ph.D., Principal Investigator , 2/1/91 - 1/1/92, $7,000 total direct costs.

NCI Travel Grant; Cost: $2,000; To participate in the 15th International Cancer Congress in Hamburg, Germany, 1990.

National Institutes of Health RO1 grant (Consortium). "Production of Anti-Idiotype Antibodies Against Human B Cell Chronic Lymphocytic Leukemia". 9/1/88-12/31/89, $42,000; M. Chatterjee, Ph.D., Principal Investigator.

Association for Research on Childhood Cancer (AROCC). "Idiotype Vaccines Against Childhood T Cell Leukemia". 1988-1989, $12,500, M. Chatterjee, Ph.D., Principal Investigator.

PDT-241. "Clinical Applications of Monoclonal Antibodies in Ovarian Cancer". American Cancer Society, 1983-1986, M. Chatterjee, Ph.D., Principal Investigator, $83,588.

ACS and BRSG Institutional Grants in 1981 ($2,000 Each).

PCM-7819545. "Radioimmunoassay for Ovarian Tumor Antigen (OCAA)". National Science Foundation. 1980-1981. M. Chatterjee, Ph.D., Principal Investigator, $15,485.

N01-CM067117. "Therapy of Patients with Ovarian Carcinomas" NCI, 1977-1979. M. Chatterjee, Ph.D., Co-Principal Investigator, $145,965.

N01-CB-64013. "The Development of Immunodiagnostic Method for the Early Detection of Ovarian Cancer in Asymptomatic Women", NIH, 1976-1979, $156,094, M. Chatterjee, Ph.D., Principal Investigator.

Recipient of four consecutive UICC Travel Grants to participate in the International Cancer Congresses held at Florence, Italy (1974); Buenos Aires, Argentina (1978); Seattle, Washington (1982); Budapest, Hungary (1986).

RESEARCH PROJECTS

Title: Idiotype Approach to Therapy of Human T Cell Leukemia, 5/1/89 - 4/30/93

Title: Monoclonal Antibody Therapy of GI Cancers, 9/30/91 - 8/31/95

Title: Structure-Function of Tumor Anti-Idiotypic Antibodies, 9/30/91 - 8/31/95

Title: New Approaches to Breast Cancer Therapy, 1/1/95 - 12/31/98

Title: Anti-Idiotype Vaccine for Breast Cancer, 12/1/94 - 11/30/97

Title: Development of Anti-Idiotype Monoclonal Antibodies for the Treatment of Breast Cancer, 7/1/94 - 6/30/97

Title: Anti-Idiotype Vaccine for Melanoma, 1/1/94 - 6/30/2001

Title: Anti-Idiotype Vaccine for Small Cell Lung Carcinoma, 7/1/94 - 6/30/2001

OTHER CREATIVE ACTIVITY

Experiences in Regulatory Affairs:

I have written Investigational New Drug Applications and obtained four INDs from FDA for the treatment of cancer patients with anti-idiotype monoclonal antibodies generated in my laboratory.

INDA Publications

1. Investigational New Drug Application for Murine Monoclonal Antibody Anti-Idiotype (4DC6) to Human T-Cell Lymphoma Glycoprotein (gp37). BB-IND # 4515 (1991).

2. Investigational New Drug Application for anti-Idiotype Antibody 3H1. "Phase 1b Study of Anti-Idiotype Monoclonal Antibody Therapy for Patients with CEA-Positive Gastrointestinal Tumors." BB-IND # 5055 (1993).

3. Investigational New Drug Application for Anti-Idiotype Antibody 11D10. "Phase Ib Study of Anti-Idiotype Monoclonal Antibody Therapy for Patients with MC-10 Positive Breast Cancer." BB-IND #5745, 1994.

4. Investigational New Drug Application for "Murine Monoclonal Antibody Anti-Idiotype (1A7) to Disialoganglioside Antigen (GD2), Saponin Component (QS-21), Intramuscular." BB-IND # 6183, 1995.

U.S. Patent Applications

1. Murine Monoclonal Anti-Idiotype Antibody 3H1 Sequences for Human Carcinoembryonic Antigen. Serial No. 08/365, 484 (Pending).

2. Murine monoclonal anti-idiotype antibody 1A7 and use for the treatment of melanoma and small cell lung carcinoma. Serial No. 08/372, 676 (Pending).

3. Murine monclonal anati-idiotype antibody 11D10 and use for the treatment of breast carcinoma. (pending)

XV. OTHER

Other Local Recognition

Special interview with Drs. Malaya Chatterjee and Kenneth A. Foon by Jerry Sanders of WKYT Television Channel 27, "On Colon Carcinoma Vaccine," which was televised during local evening news, December 28, 1993.

"U.K. Researchers Testing Cancer Vaccine" -- Article published by the Lexington Herald Leader on April 11, 1994.

Special Invitation from the National Women's Forum, Kentucky Local Chapter on Women's Health Festivals to deliver a lecture on "Immune Therapy of Breast Cancer" on September 29, 1995, at Frankfort, Kentucky, followed by an evening reception at the Governor's Mansion hosted by Governor and Mrs. Jones.

Special interview by Sky Yancey, Television Channel 36 Anchorperson, on "Breast Carcinoma Vaccine: with was televised during local evening news, January 23, 1996.

Part of #12

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Chatterjee et al.

Serial No.: 08/372,676

Filing Date: 01/07/95

For: Anti-idiotype monoclonal antibody 1A7 and use for the treatment of melanoma and small cell carcinoma

Examiner: J. Reeves

Group Art Unit: 1813

DECLARATION UNDER 37 CFR 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, SUNIL K. CHATTERJEE, Ph.D., do hereby declare as follows:

1. I have been a collaborating investigator with Malaya Chatterjee and Kenneth Foon, inventors for the above-referenced patent application.

2. I am a Member of the Markey Cancer Center in Lexington, and am an Associate Professor in the Department of Obstetrics and Gynecology, University of Kentucky. My research expertise includes the field of molecular biology and genetic engineering. A copy of my *curriculum vitae*, describing my background and qualifications, accompanies this Declaration as *Exhibit C.*

3. I have obtained the nucleic acid sequence and the corresponding amino acid sequence for the heavy and light chain variable regions of monoclonal antibody 1A7. This data, along with the method used to obtain it is provided in *Exhibit A* attached to this declaration.

4. The heavy and light chain amino acid sequences were compared using the BLAST algorithm at the National Center for Biotechnology Information with all sequences available from the PDB, SwissProt, PIR, SPUpdate, GenPept, and GPUpdate databases. The comparison was performed on December 16, 1995.

5. Amongst the 50 database sequences matched most closely to that of the 1A7 light chain variable region, none was identical. 1A7 differed from the five closest sequences by **2** substitutions at residues 50 and 55, which are contained in the second complementarity determining region (CDR2). The two differences at these positions were non-conservative substitutions, and persisted in comparisons with other light chain sequences.

Panel A of *Exhibit B* provides a comparison of the 1A7 light chain sequence with the 15 closest sequences found in the BLAST search. Residues identical to those in 1A7 are indicated with a period.

6. Amongst the 50 database sequences matched most closely to that of the 1A7 heavy chain variable region, none was identical. The following summarizes the main points deduced from the comparison.

- The closest match was with a heavy chain fragment beginning at residue 9 (designation gp|M36221|MUSIGHAEB_1). There were **6** substitutions between

residues 1 and 97 (before the VDJ junction), **6** substitutions after residue 97, and 1A7 was shorter about the VDJ junction by **2** residues.

- The closest match with a full length heavy chain variable region had the following features (designation gp|U01185|MMU01185): There were **10** substitutions between residues 1 and 97, **7** substitutions after residue 97, and 1A7 was shorter about the VDJ junction by **3** residues.
- 1A7 differed in length from all sequences but one, due to insertions or deletions of 1 to 8 residues about the VDJ junction. For the sequence of equal length (designation pir|S11106|S11106), there were **18** substitutions between residues 1 and 97, and 8 substitutions after residue 97.
- All other comparisons showed at least **14** differences between residues 1 and 97.
- All other comparisons showed at least **4** differences after residue 97.
- All other comparisons showed a total of at least **22** substitutions, insertions or deletions along the entire variable region.
- Differences appeared throughout the variable region.

Panel B of *Exhibit B* provides a comparison of the 1A7 heavy chain sequence with the 15 closest sequences found in the BLAST search.

7. Amino acid consensus sequences of the 15 most closely matched V_L and V_H regions were designed, and compared with the 1A7 sequences. This is shown in Panel C of *Exhibit B.* Identical residues are marked with a period, and CDRs are overscored with asterisks.

Other than splicing differences about the VDJ junction, there appear to be about **16** differences between 1A7 and the prototype sequences. Two of these differences are present in

the light chain; **14** are present in the heavy chain. Seven differences occur in the CDRs, while nine occur in the variable region framework.

8. The sequence data described herein were obtained no earlier than about July 24, 1995. The 1A7 sequence data have not been disclosed except under terms of confidentiality. The data were included in a recent grant application made to the National Institutes of Health under terms of confidentiality, and it is my understanding that the data will remain confidential until the grant is approved. It is my understanding that a decision on the application has not yet been rendered.

9. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

3/8/96
Date

Sunil Chatterjee
Sunil Chatterjee, Ph.D.

Exhibit A:

Sequences of 1A7

The polynucleotide sequences were obtained for the 1A7 antibody by isolating messenger RNA from the 1A7 producing cell line. For each sequence determination, total RNA was isolated from ~1 x 10^6 1A7 hybridoma cells. The yield of total RNA was about 100 μg. First strand cDNA was synthesized using SuperScript Preamplification kit (GIBCO/BRL).

To sequence the heavy chain variable region, PCRs were conducted on the cDNA using a reverse primer corresponding to amino acids 126 to 119 of the murine γ_1 constant region:

5'-CCCAAGCTTCCAGGGRCCARKGGATARACIGRTGG -3'

and various mixtures of forward primers, corresponding to the *N*-terminal leader sequences of murine variable region subgroups. The forward primer that gave a positive reaction was:

5'-ACTAGTCGACATGGCTGTCYTRGBGCTGYTCYTCTG-3'

corresponding to amino acids -20 to -12.

The amplified fragment of cDNA was subcloned into pT7 plasmid and NovaBlue competent cells were transformed using a protocol provided by the supplier (Novagen). Recombinant colonies were picked up by color selection and plasmid DNA

was prepared by miniprep procedure. The DNA sequence of the double stranded plasmid was determined using a Sequenase Version 2.0 kit (USB, Cleveland, Ohio). The sequence of the DNA insert in the plasmid was determined from both orientations using primers specific for the plasmid; namely T7 promoter (TAATACGACTCACTATAGGG) and U-19 (GTTTTCCCAGTCACGACGT). At least 8 clones were picked for sequence determination.

The sequence of the 1A7 light chain variable region was determined in a similar fashion. The forward and reverse primers giving a positive result in the PCR were:

5'-ACTAGTCGACATGAAGTTGCCTGTTAGGCTGTTGGTGCT-3'

5'-CCCAAGCTTACTGGATGGTGGGAAGATGGA-3'

corresponding to amino acids -19 to -10 of the leader sequence, and 122 to 116 of the mouse κ chain constant region.

The nucleic acid sequence and the corresponding translation for the light and heavy chain variable regions of monoclonal antibody 1A7 (along with neighboring residues of the leader and constant regions) are as follows:

1A7 light chain sequence

```
 M   K   L   P   V   R   L   L   V   L   M   F   W   I   P   A
ATG AAG TTG CCT GTT AGG CTG TTG GTG CTG ATG TTC TGG ATT CCT GCT
 S   S   D
TCC AGC GAT  (-1 to -19, leader)

 D   V   L   M   T   Q   T   P   L   S   L   P   V   S   L   G
GAT GTT TTG ATG ACC CAA ACT CCA CTC TCC CTG CCT GTC AGT CTT GGA
 D   Q   A   S   I   S   C
GAT CAA GCC TCC ATC TCT TGC  (1-23, Frame work 1)

 R   S   S   Q   S   I   V   H   S   N   G   N   T   Y   L   E
AGA TCT AGT CAG AGC ATT GTA CAT AGT AAT GGA AAC ACC TAT TTA GAA
(24-39, CDR 1)

 W   Y   L   Q   K   P   G   Q   S   P   N   L   L   I   Y
TGG TAC CTA CAG AAA CCA GGC CAG TCT CCA AAC CTC CTG ATC TAC
(40-54, Frame work 2)

 F   V   S   N   R   F   S
TTT GTT TCC AAC CGA TTT TCT (55-61, CDR 2)

 G   V   P   D   R   F   S   G   S   G   S   G   T   D   F   T
GGG GTC CCA GAC AGG TTC AGT GGC AGT GGA TCA GGG ACA GAT TTC ACA
 L   K   I   S   R   V   E   A   E   D   L   G   V   Y   Y   C
CTC AAG ATC AGC AGA GTG GAG GCT GAG GAT CTG GGA GTT TAT TAC TGC
(62-93, Frame work 3)

 F   Q   G   S   H   V   P   W   T
TTT CAA GGT TCA CAT GTT CCG TGG ACG
(94-102, CDR 3)

 F   G   G   G   T   K   L   E   I   K
TTC GGT GGA GGC ACC AAG CTG GAA ATC AAA
(103-112, Frame work 4)

 R   A   D   A   A   P   T   V   S   I   F   P   P
CGG GCT GAT GCT GCA CCA ACT GTA TCC ATC TTC CCA CCA

 S   S   K   L   G
TCC AGT AAG CTT GGG  (Constant region)
```

1A7 heavy chain sequence

```
 M   A   V   L   G   L   L   F   C   L   V   T   F   P   S   C
ATG GCT GTC TTG GGG CTG CTC TTC TGC CTG GTG ACA TTC CCA AGC TGT
 V   L   S
GTC CTG TCC  (-1 to -19, Leader)

 Q   V   Q   V   K   E   S   G   P   F   L   V   P   P   S   Q
CAG GTG CAG GTG AAG GAG TCA GGA CCT TTC CTG GTG CCC CCC TCA CAG
 S   L   S   I   T   C   T   V   S   G   F   S   L   T
AGC CTG TCC ATC ACA TGC ACT GTC TCA GGG TTC TCA TTA ACC
 (1-30, Frame work 1)

 T   Y   G   V   S
ACC TAT GGT GTA AGC  (31-35, CDR 1)

 W   I   R   Q   P   P   G   K   G   L   E   W   L   G
TGG ATT CGC CAG CCT CCA GGA AAG GGT CTG GAG TGG CTG GGA
(36-49, Frame work 2)

 A   I   W   G   D   G   T   T   N   Y   H   S   A   L   I   S
GCA ATT TGG GGT GAC GGG ACC ACA AAT TAT CAT TCA GCT CTC ATA TCC
(50-65, CDR 2)

 R   L   S   I   S   K   D   N   S   K   S   Q   V   F   L   K
AGA CTG AGC ATC AGC AAG GAT AAC TCC AAG AGC CAA GTT TTC TTA AAA
 L   N   S   L   Q   T   D   D   T   A   T   Y   Y   C   A   K
CTG AAC AGT CTG CAA ACT GAT GAC ACG GCC ACG TAC TAC TGT GCC AAA
(66-97, Frame work 3)

 L   G   N   Y   D   A   L   D   W
CTG GGT AAC TAC GAT GCT CTG GAC TAC
(98-106, CDR 3)

 W   G   Q   G   T   S   V   T   V   S   S
TGG GGT CAA GGA ACC TCA GTC ACC GTC TCC TCA
( 107-117, Frame work 4)

 A   K   T   T   P   P   P   V   Y   P   L   V   P   G   S   L
GCC AAA ACG ACA CCC CCA CCC GTC TAT CCA TTG GTC CCT GGA AGC TTG GG
(Constant region)
```

Exhibit B

Comparison of 1A7 light chain variable region with database sequences

```
1A7:      1  DVLMTQTPLSLPVSLGDQASISCRSSQSIVHSNGNTYLEWYLQKPGQSPNLLIYFVSNRF  60

 1        1  ..............................................K....K.....  60
 2        1  ..............................................K....K.....  60
 3        1  ..V...........................................K....K.....  60
 4        1  ..............................................K....K.....  60
 5        1  ..............................................K....K.....  60
 6        1  ..............................................K....K.....  60
 7        1  ..............................................K....K.....  60
 8        1  ..............................................X..K....K.....  60
 9        5  ...............................S...F...........K....K.....  64
10        1  ..............................................K....K.....  60
11        1  ..............................................K....K.....  60
12       20  ..............................................K....K.....  79
13        1  ..............................................K....K....L  60
14        1  ..............................................K....K.....  60
15        5  ...............................S...F...........K....K.....  64

1A7:     61  SGVPDRFSGSGSGTDFTLKISRVEAEDLGVYYCFQGSHVPWTFGGGTKLEIK  112

 1       61  ....................................................  112
 2       61  ....................................................  112
 3       61  ....................................................  112
 4       61  ....................................................  111
 5       61  ....X...............................................  112
 6       61  ..........................................Y.........  112
 7       61  .........C..........................................  111
 8       61  ....................................................  111
 9       65  ......................................T.............  116
10       61  ....................R.....................Y.........  112
11       61  ..........................................R.........  112
12       80  ..........................................Y...S.....  131
13       61  ..........................................Y.........  112
14       61  .......T.........................W......Y.........  112
15       65  ............................Q........T.............  116
```

DATABASE REFERENCE:

```
 1    gp| M34588|MU SIGKABR_1  Mouse Ig kappa-chain mRNA V-J regi...
 2    gp| L18941|MU SIG438B_1  Mouse rearranged immunoglobulin li...
 3    gp| Z22035|MD IGKVAH_1   immunoglobulin variable region [Mu...
 4    gp| M32857|MU SIGKCSP_1  Mouse Ig rearranged kappa-chain mR...
 5    gp| M34589|MU SIGKABS_1  Mouse Ig kappa-chain mRNA V-J regi...
 6    gp| J04438|MUSIGKCWA_1   Mouse Ig-kappa chain (PAC1) mRNA V...
 7    gp| M31271|MUSIGKCSM_1   IgM gene product [Mus musculus]
 8    gp| M32858|MUSIGKCSQ_1   Mouse Ig rearranged kappa-chain mR...
 9    gp| U29428|MMU29428_1    anti-PC Ig kappa chain [Mus musculus]
10    gp|X65770|MMIGMMM4_1     IgM gene product [Mus musculus]
11    gp|M83723|MUSIGKD2A_2    immunoglobulin kappa-chain VK-1 [M...
12   pir|B39276|B39276         Ig light chain precursor V-D-J reg...
13    gp|L14370|MUSIGKJVSA_1   immunoglobulin kappa chain [Mus mu...
14   pir|A31807|A31807         Ig kappa chain V region (PAC1) - m...
15    gp|U29267|MMU29267_1     IgL rearranged kappa chain V-J reg...
```

Comparison of 1A7 heavy chain variable region with database sequences

```
1A7:        1  QVQVKESGPFLVPPSQSLSITCTVSGFSLTTYGVSWIRQPPGKGLEWLGAIWGDGTTNYH   60

 1          1  .....G..A.................S.....V.............V.....S....   52
 2          1  ...LQ....G..A.................S..IT.V.............V.....N....   60
 3         20  ...L.....G..A.................G...N.V.............T...N.S.D.N   79
 4          1  ...L..T..G..A.................S...H.V...........VV..S..S...N   60
 5          1  ...L.....G..A.................S...H.V.............V..AG.S...N   60
 6          1  ...L.....G..A.................S...H.V.............V..AG.S...N   60
 7          1  ...L.....G..A..............P..S...D.V.............V...G.S...N   60
 8         23  ...LQ....G..A.................G...N.V.............M.....N.D.N   82
 9          1  ...L.....G..A.................G...N.V.............M.....N.D.N   60
10        133  ...LQ....G..A.................G...N.V.............M.....N.D.N  192
11         20  ...L.....G..A.................G...N.V.............M.....N.D.N   79
12          1  ...L.....G..A...............SR.S.H.V.............M...G.N.D.N   60
13         21   .HL.....V..A.................N...H.V.............V..AG.N...N   80
14         23  ...LQ....G..A.................G...N.V.............M.....N.D.N   82
15          1  ...LQ....G..A.................G...N.V.............M.....N.D.N   60


1A7:       61  SALISRLSISKDNSKSQVFLKLNSLQTDDTATYYCAKL--------GNYDALDWWGQGTSVTVSS  117

 1         53  ....................................P-----YDYExxxxx.Y.....TL..    109
 2         61  ....................................x-----xxxxxxx.K.Y.........    120
 3         80  .T.K...T.T...........M.........R....SVSIYYYGRSDK.FT..Y.........    144
 4         61  ...K.................M.........M....Rx------xx.D.Y.M.Y.........    119
 5         61  ...M.................M.........M....Rx----xxxxxx.Y.M.Y.........    120
 6         61  ...M.................M.........M....Rx------xxxx.Y.M.Y.........    118
 7         61  ...M.................M...X.....M....xx-----xxx.X.Y.M.Y.........    119
 8         83  ...K.................M...H.....R....RE--------=RDYR..Y.....T.....    138
 9         61  ...K.................M...H.....R....RE--------=RDYR..Y.....TL....    116
10        193  ...K.................M...H.....R....RE--------=RDYR..Y.....T.....    248
11         80  ...K.................M...H.....R....RE--------=RDYR..Y.....TL....    135
12         61  ...K.................M.........M....RD-------GYYDx.M.Y.........    117
13         81  ...M.................M....I....I....x-----xxxxx.Y.M.Y.........    139
14         83  ...K.................M...H.....R....RE--------=RDYR..Y.....T.....    138
15         61  ...K.................M...H.....R....RE--------=RDYR..Y.....T.....    116
```

DATABASE REFERENCE:

```
 1   gp|M36221|MUSIGHAEB_1   immunoglobulin heavy chain V-region
 2   gp|U01185|MMU01185_1    immunoglobulin heavy chain [Mus mu...
 3   sp|P01819|HV43_MOUSE    IG HEAVY CHAIN PRECURSOR V REGION ...
 4   gp|M26985|MUSIGH1PR_2   Igh gene product [Mus musculus]
 5   gp|M36217|MUSIGHADX_1   immunoglobulin heavy chain V-regio...
 6   gp|M36228|MUSIGHAEI_1   immunoglobulin heavy chain V-regio...
 7   gp|M34626|MUSIGHACK_1   Mouse Ig rearranged heavy chain (N...
 8   gp|A05515|A05515_1      Vector pSW2HPOLY DNA sequence. [un...
 9   pdb|1FDL|H              IgG1 Fab Fragment (Anti-Lysozyme A...
10   gp|L43544|MUSALCA_1     antibody [Mus musculus]
11   gp|A03907|A03907_1      antibody D1.3 V region (VDJ) [Homo...
12   pir|S38563|S38563       Ig heavy chain V region (ASWS1) - ...
13   pir|A32456|A32456       Ig heavy chain precursor V region ...
14   gp|A05504|A05504_1      pSW1 protein [unidentified] >gp|A0...
15   gp|L43544|MUSALCA_3     Mus musculus (clone pCT.kvhd1) ant...
```

Consensus analysis

```
                                                 ******************                  ******
VL consensus:     1  DVLMTQTPLSLPVSLGDQASISCRSSQSIVHSNGNTYLEWYLQKKGQSPKLLIYFVSNRF  60
1A7:              1  ..........................................P....N.........  60

                     *                                    *********
VL consensus:    61  SGVPDRFSGSGSGTDFTLKISRVEAEDLGVYYCFQGSHVPWTFGGGTKLEIK          112
1A7:             61  ..................................................          112
```

```
                                                  *****                ***********
VH consensus:     1  QVQLKESGPGLVAPSQSLSITCTVSGFSLTSYGVHWVRQPPGKGLEWLGVIWGDGSTNYN  60
1A7:              1  ...V.....F..P.................T...S.I.............A.....T...H  60

                     *****                                  ***********
VH consensus:    61  SALKSRLSISKDNSKSQVFLKMNSLQTDDTARYYCAExxxxYYAMDYWGQGTSVTVSS   119
1A7:             61  ...I.....................L.........T....KL--GN.D.L.W.........   117
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CURRICULUM VITAE

PERSONAL DATA

Name: Sunil K. Chatterjee, Ph.D.

Address: 2400 The Woods Lane
Lexington, KY-40502-6596

Date and Place of Birth: 8/7/40, Calcutta, India

Present Nationality: U.S. Citizen

Sex: Male

Marital Status: Married, two children

Wife's Name: Malaya Bhattacharya-Chatterjee, Ph.D.

Social Security Number: 174-42-8797

Telephone Numbers:

Home:	(606) 269-2225
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EDUCATION

Institute and Location	*Degree*	*Year*	*Major Field*
Presidency College, Calcutta, India	B.S.	1959	Chemistry
University of Calcutta, India	M.S.	1961	Biochemistry
University of Calcutta, India	Ph.D.	1966	Biochemistry

HONORS

University Merit List in B.S. Honors (1959) and M.S. Honors (1961), University College of Science, Calcutta, India.

Council of Scientific and Industrial Research (CSIR) Senior Fellowship Award.

Cited in Who's Who in Frontier of Science and Technology.

Cited in American Men and Women of Science.

Cited in Who's Who in South and Southwest.

Cited in Sterling Who's Who .

Cited in Who's Who in the World, 13 th. edition.

Member, Site visit team for GCRC project MO 1RR05096-08, Tulane University, New Orleans, Nov. 5-6, 1992.

Reviewer, USAMRDC Breast Cancer Program Peer Review Panel, Chemotherapy-2, Ferbruary 14-17, 1994.

External Ph.D. thesis examiner, Jadavpur University, India.

External Ph.D. thesis examiner, Calcutta University, India.

PROFESSIONAL SOCIETIES

1. American Association for Advancement of Science.

2. American Association for Cancer Research.

3. New York Academy of Sciences.

ADHOC REVIEWER FOR JOURNALS

1. Cancer Research.

2. European J. Cancer.

3. J. Obs. and Gynecol.

4. Life Sciences.

5. Cancer Investigation.

6. J. Natl. Cancer Inst.

MAJOR RESEARCH INTEREST

Cancer gene therapy /Molecular mechanism of tumor metastasis / Development of second generation anti-idiotype antibody vaccines for immuno and gene therapy of cancer.

RESEARCH EXPERIENCE

1961 - 1966	Ph.D. Thesis. University of Calcutta, Calcutta, India. Protein biosynthesis in plant mitochondria.
1966 - 1968	Post-doctoral Fellow, Department of Microbiology, University of Pennsylvania, Philadelphia. Mechanism of peptide synthesis and the role of initiation factors in the process.
1968 - 1969	Research Associate, Institute for Cancer Research,

	Fox Chase, Philadelphia. Change of the conformation of transfer RNA on aminoacylation.
1969 - 1971	Research Officer, University of Calcutta, India. Study of plant ribosomal proteins.
1971 - 1972	Research Fellow, Max-Planck Institute, Göttingen, West Germany. Characterization of ribosomal proteins from rabbit reticulocytes.
1972 - 1973	Asst. Cancer Research Scientist. Department of Pathology, Roswell Park Cancer Institute. Comparison of cell surface components of metastasizing and nonmetastatasizing rat mammary tumor cells.
1973 - 1976	Cancer Research Scientist I. Department of Pathology, Roswell Park Cancer Institute. Role of glycosyltransferases in the process of metastasis.
1976 - 1986	Cancer Research Scientist III. Department of Gynecologic Oncology, Roswell Park Cancer Institute. Study of enzymes and antigens for the early detection of ovarian cancer.
1986	National Institutes of Health Sabbatical, Laboratory of Molecular Genetics, National Institute of Child Health and Development, Cloning of genes encoding RNase H from *Salmonella typhimurium*, *Saccharomyces cerevisiae* and *Eschericia coli rnh* mutants.
1987 -1993	Cancer Research Scientist III. Department of

	Gynecologic Oncology, Roswell Park Cancer Institute. Molecular structure and expression of glycosyltransferases in normal and malignant cells. Genetic changes in the development of ovarian carcinoma.
1993	Visiting Scientist, Division of Oncology, Stanford University, Stanford, CA. Construction of expression vectors for immunoglobulin-cytokine fusion proteins.
1993-present	Associate Professor, Dept. of Obstetrics and Gynecology. Gene therapy of cancer/Molecular mechanism of cancer metastasis/ Development of second generation anti-idiotype vaccines for immuno and gene therapy of cancer.

TEACHING EXPERIENCE

Faculty member in the Department of Biochemistry, State University of New York at Buffalo. Taught research course (#BCR 687-688) entitled, "Regulation of Galactosyltransferase Expression in Ovarian Tumors". Participated in course #BCR 555-556 entitled, "Modern Biochemical Methods in Cancer Research". These courses were designed for beginning graduate students of Biochemistry as well as advanced students in other fields of biological sciences. These courses were offered twice a year (fall/spring). In these courses the theoretical basis and practical aspects of molecular biology techniques such as construction of genomic and cDNA libraries, screening of cDNA and genomic libraries, and DNA sequencing were offered.

Former Post-Doctoral Fellows:

1. Kanakendu Chowdhury, Ph.D. (1976- 1978)
   Chairman, Department of Biochemistry
   Chittaranjan National Cancer Institute
   Calcutta, India.
   Present address:
   Department of Medicine
   University of Medicine and Dentistry of New Jersey
   New Brunswick, NJ 08903

2. Aniruddha Gangopadhay, Ph.D. (1984 - 1986)
   Department of Radiology
   Shields Warren Radiation Laboratory
   Harvard Medical School
   50 Binney Street
   Boston, MA 02115

3. Sushil Mohapatra, Ph.D. (1987 - 1989)
   Director of Marketting
   Rougier Bio-Tech
   Montreal, Canada H2P 2M6

4. N. Ramachandra Swamy, Ph.D. (1989 - 1990)
   Assoc. Professor
   Department of Chemistry
   Central College
   Bangalore-560001, India.

5. Anil Puri, Ph.D. (1989 - 1990)
   Department of Physiology/Biophysics
   CWRU, School of Medicine

Cleveland, Ohio 44104

6. Sonjoy Mukerjee, Ph.D. (1991 - 1992)
Department of Molecular Immunology
Roswell Park Cancer Institute
Buffalo, NY 14263

7. Shehla Pervin, Ph.D. (1994-1995)
University of Southern California
Los Angels, CA

Present Post-doctoral Fellows:

1. Pulak K. Tripathi, Ph.D. 1992-
Markey Cancer Center
University of Kentucky
Lexington, KY 40536

2. Hongxing Qin, M.D. 1993-
Markey Cancer Center
University of Kentucky
Lexington, KY 40536

3. Chen Xu, Ph.D. 1995-
Markey Cancer Center
University of Kentucky
Lexington, KY 40536

Visiting Foreign Scientists:

Ramdas Chattopadhyay, Ph.D.
Chairman, Department of Virology

Chittaranjan National Cancer Inst.
Calcutta, India.

Dr. Chattopadhyay is visiting this laboratory for training in gene therapy with an international fellowship from the UICC.

Students

1. David Sach (Medical Student) 1974 - 1975

2. Robert Brenner (M.S. student) 1975 - 1977

3. Kathy Curan, M.S. 1976 - 1977

4. Gregory Raymond, B.S. 1988 - 1989

GRANTS

Current Support

1. National Institutes of Health, "Anti-idiotype cytokine fusion proteins as tumor vaccine". This is the part of 2 programs. Program Leader, Project II. (20% effort). Total direct cost $597,036. Description: Construct chimeric genes consisting of 11D10, an Ab2, bearing the internal image of a breast cancer-associated antigen and IL-2 /GM-CSF for therpy of breast cancer patients. Project period 02/04/95- 11/30/98.

Pending Support

1. Breast Cancer Research Program, Department of Army, "Anti-Idiotype Based Vaccine for Therapy of Breast Cancer Patients". Role, P.I., (25% effort). Total direct cost $542,985. Project period 07/1/96-06/30/00.

2. American Cancer Society, "DNA Vaccines Based on an Anti-idiotype Antibody Mimicking CEA. Role, P.I., (25% effort). Total direct cost $281,927. Project period 07/1/96-06/30/99.

3. National Institutes of Health, "Ganglioside GD2 as Target for Immunotherapy in Melanoma". Role, Co-Invest., (10% effort). Total direct cost $1,142,854. Project period 07/01/96-06/30/99.

PUBLICATIONS (MANUSCRIPTS)

1. **Chatterjee, S.K.** Protein Biosynthesis in Plant Mitochondria. Ph.D. Thesis. University of Calcutta, 1966.

2. Das, H.K., **Chatterjee, S.K.** and Roy, S.C. Protein Synthesis in Plant Mitochondria. I. Incorporation of Amino Acids in Peptide Linkage. *J. Biol. Chem.* **239**:1126-1133, 1964.

3. Das, H.K., **Chatterjee, S.K.** and Roy, S.C. Protein Synthesis in Plant Mitochondria. II. Glutamate and Glutamine Incorporation and a Study of Initial Steps and Streptomycin Effect. *Biochim. Biophys. Acta.* **87**:478-489, 1964.

4. **Chatterjee, S.K.**, Das, H.K., Roy, S.C. Deoxyribonucleic Acid and the Synthesis of Protein in Plant Mitochondia. IV. *Biochim. Biophys. Acta.* **114**:349-354, 1966.

5. **Chatterjee, S.K.,** Mukerjee, T., Das, H.K., Nath, K. and Roy, S.C. Protein Synthesis in Plant Mitochondria. V. Incorporation of Amino Acids by Submitochondrial Fractions. *Indian. J. Biol. Chem.* **3**:239-241, 1966.

6. **Chatterjee, S.K.** and Kaji, H. Conformational Changes of Transfer RNA on Aminoacylation. *Biochim. Biophys. Acta.* **224**:88-89, 1970.

7. Kazemie, M., **Chatterjee, S.K.** and Matthaei, H. Studies on Rabbit Reticulocyte Ribosomes. I. Preparation and Characterization of Ribosomal Subunits. *Hoppe-Seyler's Z. Physiol. Chem.* **354**:471-480, 1973.

8. **Chatterjee, S.K.**, Kazemie, M. and Matthaei, H. Studies on Rabbit Reticulocyte Ribosomes. II. Separation of the Ribosomal Proteins by Two Dimensional Electrophoresis. *Hoppe-Seyler's Z. Physiol. Chem.* **354**:481-486, 1973.

9. **Chatterjee, S.K.** and Kim.U. Adenosine 3':5'-Cyclic monophosphate Levels and Adenosine 3':5'-Cyclic Monophosphate Phosphodiesterase Activity in Metastasizing and Nonmetastatasizing Rat Mammary Carcinomas. *J. Natl. Cancer Inst.* **54**:181-186, 1975.

10. **Chatterjee, S.K.** and Kim. U. Biochemical Properties of Cyclic Nucleotide Phosphodiesterase in Metastasizing and Nonmetastasizing Rat Mammary Carcinomas. *J. Natl. Cancer Inst.* **56**:105-110, 1976.

11. **Chatterjee, S.K.**, Kim, U., and Bielat, K. Plasma Membrane Associated Enzymes of Mammary Tumors as the Biochemical Indicators of Metastasizing Capacity. Analysis of Enriched Plasma Membrane Preparations. *British J. Cancer* **33**:15-25, 1976.

12. **Chatterjee, S.K.** and Kim. U. Galactosyltransferase Activity in Metastasizing and Nonmetastastasizing Rat Mammary Carcinomas and Its Possible Relationship with Tumor Cell Surface Antigen Shedding. *J. Natl. Cancer Inst.* **58**:273-280, 1977.

13. Bhattacharya, M., **Chatterjee, S.K.** and Barlow, J.J. UDP-Galactose: Glycoprotein Galactosyltransferase Activity in the Ovarian Cancer Patients. *Cancer Res.* **31**:2096-2101, 1976.

14. **Chatterjee, S.K**. and Kim. U. Fucosyltransferase Activity in Metastasizing an Nonmetastasizing Rat Mammary Carcinomas. *J. Natl. Cancer Inst.* **61**:151-162, 1978.

15. **Chatterjee, S.K.**, Bhattacharya, M., and Barlow, J.J. Elevated Activity of Cytidine 5'-Monophosphate-N-Acetyl- neuraminic Acid Hydrolase in Serum of Ovarian Cancer Patients as a Possible Indicator of Malignancy. *Biochem. Biophys. Res. Commun.* **80**:826-832, 1978.

16. **Chatterjee, S.K.**, Bhattacharya, M., and Barlow, J.J. Correlation of UDP-Galactose Glycoprotein: Galactosyltransferase Levels in the Sera with the Clinical Status of Ovarian Cancer patients. *Cancer Letters* **5**:239-244, 1978.

17. **Chatterjee, S.K.**, Bhattacharya, M. and Barlow, J.J. A Simple, Specific, Radiometric Assay for 5'-Nucleotidase. *Anal Biochem.* **85**:497-506, 1979.

18. **Chatterjee, S.K.**, Bhattacharya, M. and Barlow, J.J. Glycosyltransferase and Glycosidase Activities in Ovarian Cancer Patients. *Cancer Res.* **39**:1943-1951, 1979.

19. **Chatterjee, S.K.** Glycosyltransferase Activity in Metastasizing and Nonmetastasizing Rat Mammary Tumors and the Release of these Enzymes in the Host Sera. *Eur. J. Cancer* **15**:1351-1356, 1979.

20. **Chatterjee, S.K.,** Bhattacharya, M. and Barlow, J.J. Determination of Serum Galactosyltransferase Levels in Ovarian Cancer Patients for the Evluation of the Effectiveness of Therapeutic Programs. *Cancer Letters* **8**:247-253, 1980.

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23. Choudhury, K., **Chatterjee, S.K.**, Bhattacharya, M. and Barlow, J.J. Inhibition of Galactosyltransferase by 5- Fluorouracil. *Biochem. Pharm.* **31**:459-460, 1982.

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26. Lele, S.B., Piver, M.S., Barlow, J.J., **Chatterjee, S.K.**, Schneider,S. and Ip, M. Comparison of Cytosol Estrogen Receptor Status in

Ovarian Carcinoma Using Different Radiolabeled Ligands and Methods. *J. Surg. Oncol.* **21**:155-158, 1982.

27. **Chatterjee, S.K.,** Bhattacharya, M. and Barlow, J.J. Murine Monoclonal Antibodies Against Galactosyltransferase from the Ascites of Ovarian Cancer Patients. *Cancer Res.* **44**:5723-5732, 1984.

28. Bhattacharya, M., **Chatterjee, S.K.**, Barlow, J.J. and Tsukada, Y. Identification of a Human Cancer-Associated Antigen Defined with Monoclonal Antibody *Cancer Res.* **44**:4528-4534, 1984.

29. Gangopadhyay, A., Bhattacharya, M., **Chatterjee, S.K.**, Barlow, J.J., and Tsukada, Y. Immunoperoxidase Localization of a High Molecular Weight Mucin Recognized by Monoclonal Antibody 1D3. *Cancer Res.* **45**:1744-1752, 1985.

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35. Bhattacharya-Chatterjee, M., **Chatterjee, S.K.**, Vasile, S., Seon, B.K. and Köhler, H. Idiotype Vaccines Against Human T Cell Leukemia. II. Generation and Characterization of Monoclonal Idiotype Cascade (Ab1, Ab2, Ab3). *J. Immunol.* **141**:1398-1403, 1988.

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37. Gangopadhyay, A., **Chatterjee, S.K.**, Bhattacharya, M. and Barlow, J.J. Characterization of the Antigen Recognized by Monoclonal Antibody 1D3. *Cancer Biochem. Biophys.* **10**:107-115, 1988.

38. **Chatterjee, S.K.** Molecular Cloning of Human β-1,4-Galtoslytransferase and Expression of Catalytic Activity of the Fusion Proteins in Eschericia coli. *Int. J. Biochem.* **23**:695-702, 1991.

39. Itay, M., McKelvin, D., **Chatterjee, S.K.** and Crouch, R.J. Cloning of Genes Encoding RNase H from Salmonella typhimurium, Saccharomyces cerevisiae and Eschericia coli rnh Mutants. *Molec. Gen. Genetics.* **227**:438-445, 1991.

40. Tripathi, P.K. and **Chatterjee, S.K**. Simple Method for Preparing Pure Lambda Phage DNA. *Methods in Mol. Cell. Biol.* **3**:232-238, 1993.

41. **Chatterjee, S. K.** and Tripathi, P.K. Genes associated with metastasis in ovarian cancer. *Proc. Int. Cancer Congress* **3**:2371-2375, 1994.

42. **Chatterjee, S.K.**, Mukerjee, S and Tripathi, P.K. Analysis of the sequences of human β-1,4-Galactosyltransferase cDNA clones. *Int. J. Biochem. Cell Biol.* **27**:329-336, 1995.

43. Tripathi, P.K. and **Chatterjee, S.K.** Identification of genes associated with metastasis in ovarian cancer (In press in *Cancer investigation*).

44. Qin,H-X and **Chatterjee, S.K.** Construction of recombinant vaccinia virus expressing GM-CSF and its use as tumor vaccine. (In press in *Gene Therapy*).

45. Qin H-X. and **Chatterje, S.K.** Recombinant vaccinia virus expressing Interleukin-2 for cancer gene therapy (re-submitted after revision in *Cancer Gene Therapy*).

46. Qin H-X. and **Chatterjee, S.K.** Cancer gene therapy using tumor cells transfected with recombinant vaccinia virus expressing GM-CSF. (communicated to *Int. J. cancer*).

ABSTRACTS

1 Gualerzi, C., Igarashi, K., **Chatterjee, S.K.**, and Kaji, A. A New Factor Which Releases Aminoacyl tRNA from the Complex of Aminoacyl tRNA and 30 Subunits. Proc. Am. Soc. Microbiol. 1970.

2. Kim, U. and **Chatterjee, S.K.** Role of Host Immunological Surveillance System in the Development of Metastasizing Mammary Carcinomas and Mechanism of Metastasis. Proc. 9th Meeting on Mammary Cancer in Expt. Animals and Man. 1973.

3. **Chatterjee, S.K.** and Kim. U. Cyclic Nucleotide Phosphodiesterase (cPDE) Activity in Metastasizing and Nonmetastasizing Rat Mammary Carcinomas (MT). Proc. Am. Assoc. Cancer Res. 15:130, 1974.

4. Kim, U., **Chatterjee, S.K.** and Chatterjee, M. Study of the Spontaneously Regressing Property of an Established Metastasizing Rat Mammary Carcinoma. Proc. Conf. Breast Cancer Task Force, Pisa, Italy, 1974.

5. Kim, U. and **Chatterjee, S.K.** Biological Significance of Cyclic Adnosine 3':5'-Monophosphate (cAMP) Levels in Cancer: Correlation with Surface Antigen Dissociability, Immunogenicity, and Metastasizing Capacity of Mammary Tumor Cells. Xith International Cancer Cong. 4:640, 1974.

6. **Chatterjee, S.K.**, Kim, U., and Sproul, E.E. Cyclic Nucleotide Phosphodiesterase (cDPE) Activity and Its Effect on Cell Surface Properties of Metastasizing and Nonmetastasizing Rat Mammary Tumors (MT). Proc. Am. Assoc. Cancer Res. 16:198, 1975.

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8. **Chatterjee, S.K.**, Bhattacharya, M. and Barlow, J.J. Glycoprotein Glycosyltransferase (GT) and Glycosidase (GS) Activities in the Ovarian Cancer Patient. Proc. Am. Assoc. Cancer Res. 19:165, 1978.

9. **Chatterjee, S.K.**, Bhattacharya, M. and Barlow, J.J. Use of Cytidine 5'-Monophospho-N-Acetyl Neuraminic Acid (CMP-NANA) Hydrolase Assay in Serum as an Indicator of Malignancy in Ovarian Carcinoma XIIth International Cancer Congress. Oct. 5-11, 1978, Buenos Aires, Argentina.

10. Bhattacharya, M., Barlow, J.J. and **Chatterjee, S.K.** Use of Ovarian Tumor-Associated Antigens for the Detection and Management of Ovarian Carcinoma. XIIth International Cancer Congress, Oct 5-11, 1978, Buenos Aires, Argentina.

11. **Chatterjee, S.K.**, Bhattacharya, M. and Barlow, J.J. Possible Use of Galactosyltransferase (GT) Assay in the Sera of Ovarian Cancer Patients for Evaluation of the Effectiveness of Therapeutic Programs. Proc. Am. Assoc. Cancer Res. 20:42, 1979.

12. **Chatterjee, S.K.**, Chowdhuri, K., Bhattacharya, M., and Barlow, J.J. β-Hexosaminidase (Hex) Isoenzymes in Homogenates from Normal Human Ovary and Ovarian Adenocarcinoma. Proc. Am. Assoc. Cancer Res. 31:26, 1980.

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14. **Chatterjee, S.K.**, Bhattacharya, M., and Barlow, J.J. Purification of Glycoprotein: Galactosyltransferase (GT from Ascitic Fluids of Patients with Epithelial Ovarian Carcinoma. Proc. Am. Assoc. Cancer Res. 22:20:1981.

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16. Bhattacharya, M., **Chatterjee, S.K.**, Barlow, J.J. and Fuji, H. Identification of a Human Cancer-Associated Glycoprotein, GP-48 Defined with Monoclonal Antibody. Proc. Am. Assoc. Cancer Res. 23:276, 1982

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